The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	3D Dynamic and Patient-Centered Outcomes of Facial Reanimation Surgery in Patients with Facial Paralysis
Principal Investigator:	**Carroll Ann Trotman, BDS, MA, MS,**

Sponsor: NIH

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

We invite you to take part in a research study involving the evaluation of facial paralysis because you are a patient at the Facial Nerve Center (FNC) at Massachusetts Eye and Ear Infirmary (MEEI). In this study, we would like to determine how well facial reanimation surgery works for patients who need the surgery and find out the changes in facial soft tissue movements over time and how patients feel about their face and general health before and after the surgery. We will ask you to attend for three visits, one before the surgery and two additional visits at approximately 5 months and 18 months after your surgery. At each visit we will take images of your face at rest and during different facial soft tissue movements so that we can measure the movements. To do this, we will place small dots on your face and ask you to make the movements and take pictures and videos of your face while you make the movements.

1. Why is this study being done?

Facial paralysis is the loss of facial movement due to a weakened or damaged facial nerve. The resultant disfigurement and impairment in soft tissue movements not only impacts facial esthetics and function, but also patients' social and emotional quality of life. Treatments can range from non-surgical interventions to facial reanimation surgery.

Surgeries for facial reanimation can have a tremendous impact on patients' lives. For the surgery, muscle may be transferred to the face and/or nerves may be modified. This study will focus on different outcomes of the surgery.

2. How many people will take part in this study?

96 people.

3. What will happen if I take part in this study?

Your surgeon and/or the research assistant at MEEI will first determine if you are eligible to participate in the study and will confirm that you are willing to be contacted by staff at Ohio State to hear more about the study. If you say yes, then Ohio State staff

will contact you to explain the study, confirm your eligibility, and set an appointment for you to visit the Facial Animation laboratory (FAL) in Boston. Your consent to participate in the study will be obtained by the Ohio State staff, and testing and collection of data will be done by Ohio State staff and will occur at the FAL laboratory. For the tests, you will be asked to make a series of facial movements and we will take images of your face during these movements.

Visit 1: Baseline (Before surgery); about 1 hour and 45 minutes

You will be instructed by the study staff to read this informed consent form (ICF) and given time to have any questions answered. Then you will be instructed to sign the ICF and will be given a copy. You will be asked to complete a medical history and provide demographic information.

You will provide us with your contact information, as well as the contact information of someone else you know, so that we can reach you in case of communication challenges to schedule or re-schedule appointments during the course of the study. You then will be screened according to inclusion/exclusion criteria.

The inclusion/exclusion criteria are as follows.

(a) Inclusion criteria. 1) Patients with unilateral facial paralysis scheduled for smile reconstruction using free gracilis muscle transfer driven by one of four neuronal inputs (1) the trigeminal nerve (nV), (2) a cross-face nerve (nVII), (3) dual innervation combining the trigeminal nerve and a cross face nerve, and (4) manipulations that involve performing direct coaptation between the trigeminal nerve and a branch to the native zygomaticus major muscle (5- 7 transfer) along with selective neurolysis in which several facial nerve branches that innervate muscles antagonistic to the smile animation are transected—this innervation group is termed “midfacial modification”. 2) Patient willingness to participate in the study. 3) An ability to comprehend verbal instructions. 4) An age range of 18 to 75 years.

(b) Exclusion criteria. 1) Presence of a major facial deformity/condition either congenital or acquired e.g. hemifacial microsomia, cancer. 2) Facial movement disorders due to primary muscular dysfunction or hemifacial spasm in the absence of synkinesis; or 3) Mental or

hearing impairment to the extent that comprehension or ability to perform the tests is hampered.

You will be asked to complete three forms. One will ask you questions about how you feel about the way your face moves. This will take about 6 minutes to complete. Next, you will be asked to complete a form with questions about how you feel about your overall health and well-being. This will take about 8 minutes to complete. And lastly you will be asked to complete a form with questions about general problems with your face, mouth, jaw joints as well as your social interactions and physical appearance. This will take about 6 minutes.

Facial movements will be measured using a motion capture system. Small dots will be put and held in place on your face with an organic adhesive glue. Although the adhesive glue does not contain latex, we will test for possible allergy prior to placement on the face by placing a small amount of the glue on the back of your hand and wait for 15 minutes to see if there is a reaction. If there is a reaction, the study team will treat the affected area with 1% hydrocortisone cream, and instead medical double-sided tape will be used to hold the dots in place. Then, photographs of your face will be taken with the 3D camera, and video images will be recorded during each series of facial movements. Remote monitoring may occur through a secure Zoom or Teams meeting to ensure quality of visit. No video of patient will be recorded and will only be monitored by the principal investigator (PI) from a private/secure location to ensure patient's privacy.

After your first test visit, you will have your surgery. Your surgery is not being performed as part of this research.

Visit 2: 5 Months after Surgery; about 1 hour and 45 minutes

Your medical history will be reviewed and any changes will be noted. Facial movements will be re-measured using the motion capture system in the same fashion as during visit 1.

Visit 3:18 Months after Surgery; about 1 hour and 45 minutes

Your medical history will be reviewed and any changes will be noted.

You will be asked again to complete the three forms about how you feel about the way your face moves, about your overall health and well-being, and about general problems with your face, mouth, jaw joints as well as your social interactions and physical appearance in the same fashion as done at visit 1. Facial movements will be re-measured using the motion capture system in the same fashion as during visit 1.

4. How long will I be in the study?

We expect that you will be in this research study for 3 visits over 18 months. Each visit will last approximately one hour and 45 minutes for an approximate total of six hours over the three visits.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

As with any research study there is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

There are no known risks associated with the collection of clinical treatment details, 3D photographs, video images, or questionnaires. There is a very small risk of allergic reaction to the adhesive which is non-latex based eyelash adhesive. To manage this

potential risk, we test for an allergic reaction by placing a small amount of the glue on the back of your hand and wait for 15 minutes to see if you have a reaction. If you do have a reaction, we will treat the affected area with 1% hydrocortisone cream. We will then use double sided adhesive tape to help hold the dots on your face. Because you are having surgery to correct your facial paralysis, you are aware of the inability to move your face during expressions. The information that we ask in the forms simply tracks your feeling and how your facial movements are improving over time, as such the risks associated with the forms are minimal.

7. What benefits can I expect from being in the study?

There are no direct benefits to you for taking part in this study. However, the information gained from this study has potential to benefit others due to our enhanced understanding of facial reanimation surgery.

8. What other choices do I have if I do not take part in the study?

Participation in research is completely voluntary. You can decide to participate or not to participate in the research at any time for any reason. You are able to receive surgery outside of your participation in this study.

Also, if you refuse to participate in the study or stop being in this study, it will not affect your care or treatment outside this study, payment for your health care, or your health care benefits.

9. What are the costs of taking part in this study?

The costs will include travel costs associated with participation in this study. You and/or your insurance plan will be responsible to pay for the costs of your regular medical care and facial surgery which is being performed as part of standard medical care.

10. Will I be paid for taking part in this study?

By law, payments to participants are considered taxable income.

You will receive a payment of $500 at the completion of each study visit. There will be 3 study visits for a total of up to $1500 payment for your participation.

Payment will be made through direct bank deposit or by mailing a check. We will make a deposit or send a check after every completed visit.

In order to receive a deposit, a bank statement or blank check must be provided, it takes 48-72 hrs. To receive a direct deposit, otherwise, a check will be mailed to the address provided within two to three weeks after completion of the visit.

A $40 USD stipend will be provided as pre-paid debit card and will be given after each visit to reduce parking expenses. You may use this card at any store that accepts credit cards. All cards will be activated before we give them to you. The debit cards are available for use immediately once you receive them.

Due to federal tax law, you are required to provide us with your social security number to process your payments.

A T-shirt will also be provided at the end of the first visit.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

Your de-identified information may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

Certificate of Confidentiality for this study. The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions. You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:

  Physical exams

  Laboratory, x-ray, and other test results

  Diaries and questionnaires

  The diagnosis and treatment of a mental health condition
- Records about any study drug you received;
- Records about the study device; and

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or

- owned by the sponsor.

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others: Sponsor *NIH/NIDCR, the PI (Carroll Ann Trotman), Co-Investigators (Derrick Lin, Ching-Chang Ko), Research Assistants (Kevin Matlack and Lana Elgaddafi) who analyze health information for the study*.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and

- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact the Principal Investigator Carroll Ann Trotman at 614-292-9755 or Trotman.13@osu.edu.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the Principal Investigator Carroll Ann Trotman at 614-292-9755 or Trotman.13@osu.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Carroll Ann Trotman at 614-292-9755 or Trotman.13@osu.edu or Ching-Chang Ko at 614-688-3146 or Ko.367@osu.edu**.**

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant** **AM/PM** **Date and time**
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant** **(when applicable)** **AM/PM** **Date and time**
Relationship to the participant	

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM

Date and time

Printed name of witness

Signature of witness

AM/PM

Date and time